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Art Unit: 1618

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of the Claims

1. (currently amended) A non-aqueous particle-forming composition comprising a modafinil compound and at least one surfactant, wherein contacting said non-aqueous particle-forming composition ~~is a self-emulsifying drug delivery system which~~ with an aqueous medium spontaneously forms an aqueous, homogeneous, stable composition of non-crystalline particles comprising the modafinil compound ~~when said composition is contacted with an aqueous medium~~.

2. (currently amended) ~~An~~The aqueous, homogeneous, stable composition of claim 1~~comprising non-crystalline particles comprising a modafinil compound, wherein said composition is optically isotropic and thermodynamically stable~~.

3. (original) The composition of claims 1 or 2, wherein the modafinil compound is modafinil.

4. (original) The composition of claims 1 or 2, wherein the composition is pharmaceutically acceptable.

5. canceled.

6. canceled.

7. canceled.

8. (currently amended) The composition of claims [7]1 or 2, wherein the surfactant or surfactants comprise from about 0.5% to about 50% (w/w) of the non-aqueous particle-forming composition.

9. (currently amended) The composition of claim 8, wherein the surfactant or surfactants comprise from about 1% to about 20% (w/w) of the non-aqueous particle-forming composition.

10. (currently amended) The composition of claims [7]1 or 2, wherein the surfactant or surfactants is a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a saturated polyglycolized glyceride, a fatty acid ester of polyethylene glycol, a medium chain monoglyceride, a medium chain fatty acid ester, d-α-tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, or an ethoxylated hydroxystearic acid.

11. (original) The composition of claim 10, comprising a second surfactant.

12. (original) The composition of claim 11, wherein the second surfactant is a polyoxyethylene sorbitan fatty acid ester.

13. (original) The composition of claim 12, wherein the second surfactant is sorbitan monolaurate or Polysorbate 80.

14. (original) The composition of claims 1 or 2, further comprising an organic solvent.

15. (original) The composition of claim 14, wherein the organic solvent is glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, a medium chain length monoglyceride, or a polyethylene glycol.

16. (original) The composition of claim 15, further comprising benzyl alcohol, α-phenethyl alcohol or β-phenethyl alcohol.

17. (currently amended) The composition of claim 3, wherein modafinil is present in

the non-aqueous particle-forming composition at a concentration of about 1 to about 500 mg/ml.

18. (currently amended) The composition of claim 17, wherein modafinil is present in the non-aqueous particle-forming composition at a concentration of about 1 to about 200 mg/ml.

19. (currently amended) The composition of claims 1 or 2, wherein the non-aqueous particle-forming composition comprises a modafinil compound ~~is present~~ at a concentration of about 1 to about 100 mg/ml; a first surfactant selected from a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, a medium chain monoglyceride, a medium chain fatty acid ester, d-α-tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, and an ethoxylated hydroxystearic acid; a second surfactant selected from a polyoxyethylene sorbitan fatty acid ester; and an organic solvent selected from glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, a medium chain length monoglyceride, and a polyethylene glycol.

20. (original) The composition of claim 19, wherein the modafinil compound is modafinil.

21. (original) The composition of claim 20, wherein the first surfactant is a saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, or a medium chain monoglyceride; the second surfactant is a polyoxyethylene sorbitan fatty acid ester; and the organic solvent is a polyethylene glycol.

22. (original) The composition of claim 21, wherein the first surfactant is glyceryl caprylate/caprate, glyceryl monocaprylate or polyethoxylated (40) stearic acid; the second surfactant is sorbitan monolaurate; and the organic solvent is PEG-300 or PEG-400.

23. (currently amended) The composition of claim 22, wherein the non-aqueous particle-forming composition comprises 90% PEG-400, 5% sorbitan monolaurate, 5% glyceryl caprylate/caprate (w/w/w).

24. (currently amended) The composition of claim 22, wherein the non-aqueous particle-forming composition comprises 90% PEG-400, 5% sorbitan monolaurate, 5% glyceryl monocaprylate (w/w/w).

25. (currently amended) The composition of claim 22, wherein the non-aqueous particle-forming composition comprises 90% PEG-400, 5% sorbitan monolaurate, 5% polyethoxylated (40) stearic acid (w/w/w).

26. (original) The composition of claim 21, wherein the first surfactant is glyceryl caprylate/caprate, glyceryl monocaprylate, polyethoxylated (40) stearic acid or a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate; the second surfactant is polyoxyethylene (80) sorbitan monooleate; and the organic solvent is PEG-300 or PEG-400.

27. (currently amended) The composition of claim 26, wherein the non-aqueous particle-forming composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl caprylate/caprate (w/w/w).

28. (currently amended) The composition of claim 26, wherein the non-aqueous particle-forming composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl monocaprylate (w/w/w).

29. (currently amended) The composition of claim 26, wherein the non-aqueous particle-forming composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% polyethoxylated (40) stearic acid (w/w/w).

30. (currently amended) The composition of claim 26, wherein the non-aqueous

particle-forming composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% of a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate (w/w/w).

31. (original) The composition of claim 10, wherein the composition comprises Polysorbate 80, glyceryl caprylate/caprate and a mixture of glyceryl tricaprate and glyceryl tricaprilate.

32. (original) The composition of claims 1 or 2, comprising one or more unit doses of a modafinil compound.

33. (original) The composition of claim 32, comprising one unit dose of a modafinil compound.

34. (previously presented) The composition of claim 33, wherein the unit dose comprises 200 mg of a modafinil compound.

35. (previously presented) The composition of claim 33, wherein the unit dose comprises 100 mg of a modafinil compound

36. (currently amended) A method of preparing [a] an aqueous, homogeneous, stable composition of non-crystalline particles, wherein the particles comprise a modafinil compound, comprising contacting a non-aqueous particle-forming composition of claim 1 with an aqueous medium.

37. (currently amended) The method of claim 36, wherein the non-aqueous particle-forming composition of claim 1 is contacted with an aqueous medium in vitro.

38. (currently amended) The method of claim 36, wherein the non-aqueous particle-forming composition of claim 1 is contacted with an aqueous medium in vivo.

39. (original) The method of claim 36, wherein the modafinil compound is modafinil.

40. (currently amended) A method of preparing [a] an aqueous, homogeneous, stable composition of non-crystalline particles, wherein the particles comprise a modafinil compound, comprising:

(a) dissolving a modafinil compound in a liquid comprising at least one surfactant in an amount from about 1% to about 50%, to form a non-aqueous particle-forming composition of claim 1; and

(b) contacting the non-aqueous particle-forming composition with an aqueous medium to form the composition of non-crystalline particles.

41. (currently amended) A method of treating a disease or disorder in a subject, comprising administering a therapeutically effective amount of a non-aqueous particle-forming composition of claim 1 ~~comprising at least one surfactant~~ to a subject.

42. (currently amended) A method of treating a disease or disorder in a subject, comprising:

(a) contacting a non-aqueous particle-forming composition of claim 1, ~~further comprising at least one surfactant~~ with an aqueous medium, thereby forming [a] an aqueous, homogeneous, stable composition of non-crystalline particles, wherein the particles comprise a modafinil compound; and

(b) administering a therapeutically effective amount of the aqueous, homogeneous, stable composition of non-crystalline particles to a subject.

43. (original) The method of claims 40, 41 or 42, wherein the modafinil compound is modafinil.

44. (previously presented) The method of claim 41 or 42, wherein the composition is administered for the treatment of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive

dysfunction or fatigue; or for the promotion of wakefulness, stimulation of appetite, or stimulation of weight gain to a patient in need thereof.

45. (original) The composition of claim 3, wherein upon administration of the composition to a subject in need thereof, modafinil has a blood serum level of about 0.05 to about 30 μg/ml in said subject.

46. (original) The composition of claim 45, wherein the blood serum level is from about 1 to about 20 μg/ml.

47. (currently amended) The composition of claim 1, wherein the non-aqueous particle-forming composition is suitable for oral administration to a subject.

48. (currently amended) The composition of claim 47, wherein the non-aqueous particle-forming composition is encapsulated within a capsule.

49. (original) The composition of claim 48, wherein the capsule is a soft gelatin capsule.

50. (original) The composition of claim 48, wherein the capsule is a hard capsule.

51. (currently amended) The composition of claim 2, wherein the aqueous, homogeneous, stable composition is suitable for oral administration to a subject.

52. canceled.

53. canceled.

54. canceled.

55. (previously presented) The composition of claims 1, 2, or 19 wherein the modafinil compound is the levorotatory form of modafinil.

56. (previously presented) The method of claim 36, wherein the modafinil compound is the levorotatory form of modafinil.

57. (previously presented) The composition of claims 40, 41, or 42, wherein the modafinil compound is the levorotatory form of modafinil.

58. (previously presented) The composition of claims 40, 41, or 42 wherein the modafinil compound is modafinil.